

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventors: **David J. Ecker, et al.**

Serial No.: **Not yet assigned**

Group Art Unit: **1637**

Filed: **Concurrently herewith**

Examiner: **Suryaprabha Chunduru**

Title: **METHODS FOR RAPID DETECTION AND IDENTIFICATION OF
BACTERIAL BIOAGENTS**

EXPRESS MAIL INFORMATION

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DATE OF DEPOSIT: March 25, 2004

Mail Stop: Patent Application
Commissioner for Patents
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Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

S I R :

Pursuant to 37 C.F.R. §§ 1.97 and 1.98 and to the duty of disclosure set forth in 37 C.F.R. § 1.56, the Examiner in charge of the above-identified application is requested to consider and make of record the references listed on the attached PTO-1449 forms submitted herewith.

Although the information submitted herewith may be "material" to the Examiner's consideration of the subject application, this submission is not intended to constitute an admission that such information is "prior art" as to the claimed invention.

Copies of the references cited on the attached PTO/SB/08A and PTO-892 forms can be found in the parent case, U.S. Serial No. 10/326,642, filed December 18, 2002.

In accordance with 37 C.F.R. § 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

No first Official Action has yet been received and it is presumed that none has yet been mailed. No fee or certification is required. 37 C.F.R. § 1.97(b).

Respectfully submitted,



Paul K. Legaard
Regis. No. 38,534

Enclosures:

PTO/SB/08A – 8 Sheets
PTO-892 (1 Sheet)

Dated: March 25, 2004

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Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Sheet

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of

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Complete If Known

Application Number	10/326,642
Filing Date	December 18, 2002
First Named Inventor	David J. Ecker
Group Art Unit	Not Yet Assigned
Examiner Name	Not Yet Assigned
Attorney Docket Number	IBIS0001-106

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			
	AA	US-5,484,908	01/16/1996	Froehler et al	
	AB	US- 5,502,177	03/26/1996	Matteucci et al	
	AC	US- 5,547,835	08/20/1996	Koster	
	AD	US- 5,605,798	02/25/1997	Koster	
	AE	US- 5,622,824	04/22/1997	Koster	
	AF	US- 5,645,985	07/08/1997	Froehler et al	
	AG	US- 5,691,141	11/25/1997	Koster	
	AH	US- 5,763,588	07/09/1998	Matteucci et al	
	AI	US- 5,830,853	11/03/1998	Froehler et al	
	AJ	US- 5,849,492	12/15/1998	Rogan	
	AK	US- 5,872,003	02/16/1999	Koster	
	AL	US- 5,965,363	10/12/1999	Monforte et al	
	AM	US- 6,005,096	12/21/1999	Matteucci et al	
	AN	US- 6,007,992	12/28/1991	Lin et al	
	AO	US- 6,028,183	02/22/2000	Lin et al	
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ³
		Country Code ² - Number ⁴ - Kind Code ⁵ (if known)				
	BA	WO97/33000	09/12/97			
	BB	WO97/37041	10/09/97			
	BC	WO98/12355	03/26/98			
	BD	WO98/54751	12/03/98			
	BE	WO99/14375	03/25/99			
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Attorney Docket Number	IBIS0001-106

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	CA	Aaserud, D.J., et al., "Accurate base composition of double-strand DNA by mass spectrometry," J. Am. Soc. Mass Spec., 1996, 7, 1266-1269	
	CB	Bowen, J.E., et al., "The native virulence plasmid combination affects the segregational stability of a theta-replicating shuttle vector in bacillus anthracis var. New Hampshire," J. Appl. Microbiol., 1999, 87, 270-278	
	CC	Hurst, G.B., et al., "Detection of bacterial DNA polymerase chain reaction products by matrix-assisted laser desorption/ionization mass spectrometry," Rapid Commun. Mass Spec., 1996, 10, 377-382	
	CD	Loakes, D., et al., "Nitroindoles as universal bases," Nucleosides and Nucleotides, 1995, 14(3-5), 1001-1003	
	CE	Muddiman, D.C., et al., "Precise mass measurement of a double-stranded 500 base-pair (309 kDa) polymerase chain reaction product by negative ion electrospray ionization fourier transform ion cyclotron resonance mass spectrometry," Rapid Commun. Mass Spec., 1999, 13, 1201-1204	
	CF	Muddiman, D.C., et al., "Length and base composition of PCR-amplified nucleic acids using mass measurements from electrospray ionization mass spectrometry," Anal. Chem., 1997, 69, 1543-1549	
	CG	Sala, M., et al., "Ambiguous base pairing of the purine analogue 1-(2-deoxy-β-D -ribofuranosyl)-imidazole-4-carboxamide during PCR," Nucl. Acids Res., 1996, 24(17), 3302-3306	
	CH	Van Aerschot, A., et al., "In search of acyclic analogues as universal nucleosides in degenerate probes," Nucleosides and Nucleotides, 1995, 14(3-5), 1053-1056	
	CI	Wunschel, D.S., et al., "Heterogeneity in bacillus cereus PCR products detected by ESI-FTICR mass spectrometry," Anal. Chem., 1998, 70, 1203-1207	
	CJ	Mushegian, A.R., et al., "A minimal gene set for cellular life derived by comparison of complete bacterial genomes," Proc. Natl. Acad. Sci. USA, 1996, 93, 10268-10273	
	CK	Welham, et al., Rapid Communications in Mass Spectroscopy (1988) 12:176-180	

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Examiner Name	Not Yet Assigned
Attorney Docket Number	IBIS0001-106

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	CL	Cho et al., "Application of the ribonuclease P (RNaseP) RNA gene sequence for phylogenetic analysis of the genus <i>Saccharomonospora</i> ," <i>Int'l. J. Systematic Biol.</i> (1998) 48:1223-1230	
	CM	Matray, et al., "Synthesis and properties of RNA analogs - oligoribonucleotide N3'->P5' phosphoramidates," <i>Nucleic Acids Res.</i> (1999) 3976-3985	
	CN	Li, et al., "Single nucleotide polymorphism determination using primer extension and time of flight mass spectrometry," <i>Electrophoresis</i> (1999) 20:1258-1265	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Application Number	10/326,642
		Filing Date	December 18, 2002
		First Named Inventor	David J. Ecker
		Group Art Unit	1637
		Examiner Name	S. Chunduru
Sheet 1 of 5	Attorney Docket Number	IBIS0001-106 (TIGR0005US)	

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	S1	BAKER, et al., "Review and re-analysis of domain-specific 16S primers," J. Microbiol. Methods (2003) 55:541-555.	
	S2	BENSON, et al., "Advantages of Thermococcus kodakaraensis (KOD) DNA polymerase for PCR-mass spectrometry based analyses," J. Am. Soc. Mass Spectrom. (2003) 14:601-604.	
	S3	BLACK, et al., "Detection of trace levels of tricothecene mycotoxins in human urine by gas chromatography-mass spectrometry," J. Chromatog. (1986) 367:103-115.	
	S4	CAMPBELL and HUANG, "Detection of California serogroup Bunyavirus in tissue culture and mosquito pools by PCR," J. Virol. Methods (1996) 57:175-179.	
	S5	CHEN, et al., "A universal PCR primer to detect members of the Polyviridae and its use to examine the taxonomic status of several members of the family," Arch. Virol. (2001) 146:757-766.	
	S6	CONRAD, et al., "16S-23S rDNA internal transcribed spacer sequences for analysis of the phylogenetic relationships among species of the genus Fusobacterium," Intl. J. System. Evol. Microbiol. (2002) 52:493-499.	
	S7	DASEN, et al., "Classification and identification of Propionibacteria based on ribosomal RNA genes and PCR," System. Appl. Microbiol. (1998) 21:251-259.	
	S8	DEFORCE, et al., "Characterization of DNA oligonucleotides by coupling of capillary zone electrophoresis to electrospray ionization Q-TOF mass spectrometry," Anal. Chem. (1998) 70:3060-3068.	
	S9	DEMASURE, et al., "A set of universal primers for amplification of polymorphic non-coding regions of mitochondrial and chloroplast DNA in plants," Mol. Ecol. (1995) 4:129-131.	
	S10	FLORA, et al., "Dual-micro-ESI source for precise mass determination on a quadrupole time-of-flight mass spectrometer for genomic and proteomic applications," Anal. Bioanal. Chem. (2002) 373:538-546.	
	S11	FOX, et al., "Identification of Brucella by ribosomal-spacer-region PCR and differentiation of Brucella cells from other Brucella spp. pathogenic for humans by carbohydrate profiles," J. Clin. Microbiol. (1998) 36:3217-3222.	

Examiner Signature	Date Considered
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	S12	FOX et al., "Report of the Bioterrorism Workshop", J. Microbiol. Methods (2002) 51:247-254.	
	S13	GRIFFEY and GREIG, "Detection of base pair mismatches in duplex DNA and RNA oligonucleotides using electrospray mass spectrometry," SPIE (1997) 2985:82-86.	
	S14	GRIFFIN, et al., "Direct genetic analysis by matrix-assisted laser desorption/ionization mass spectrometry," proc. Natl. Acad. Sci. USA (1999) 96:6301-6306.	
	S15	HANNIS and MUDDIMAN, "Accurate characterization of the tyrosine hydroxylase forensic allele 9.3 through development of electrospray ionization Fourier transform ion cyclotron resonance mass spectrometry," Rapid. Comm. Mass Spectrom. (1999) 13:954-962.	
	S16	HANNIS and MUDDIMAN, "Genotyping short tandem repeats using flow injection and electrospray ionization Fourier transform ion cyclotron resonance mass spectrometry," Rapid. Comm. Mass Spectrom. (2001) 15:348-350.	
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	S18	HAYASHI, et al., "Phylogenetic analysis of the human gut microbiota using 16S rDNA clone libraries and strictly anaerobic culture based methods," Microbiol. Immunol. (2002) 46:535-548.	
	S19	HOFFMANN, et al., "Universal primer set for the full-length amplification of all influenza A viruses," Arch. Virol. (2001) 146:2275-2289.	
	S20	ISOLA, et al., "MALDI-TOF mass spectrometric method for detection of hybridized DNA oligomers," Anal. Chem. (2001) 73:2126-2131.	
	S21	JANKOWSKI and SOLER, "Mass spectrometry of DNA: Part 2" Quantitative estimation of base composition," Eur. J. Mass Spectrom. Biochem. Med. Environ. Res. (1980) 1:45-52.	
	S22	KAGEYAMA and BENNO, "Rapid detection of human fecal Eubacterium species and related genera by tested PCR method," Microbiol. Immunol. (2001) 45:315-318.	

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OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

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	S23	LITTLE, et al., "Rapid sequencing of oligonucleotides by high-resolution mass spectrometry," J. Am. Chem. Soc. (1994) 116:4893-4897.	
	S24	LIU, et al., "Improving the microdialysis procedure for electrospray ionization mass spectrometry of biological samples," J. Mass Spectrom. (1997) 32:425-431.	
	S25	MANGRUM, et al., "Solution composition and thermal denaturation for the production of single-stranded PCR amplicons: piperidine-induced destabilization of the DNA duplex," J. Am. Soc. Mass Spectrom. (2002) 13:232-240.	
	S26	McCABE, et al., "Bacterial species identification after DNA amplification with a universal primer pair," Mol. Genet. Metab. (1999) 66:205-211.	
	S27	MEIYU, et al., "Detection of flaviviruses by reverse transcriptase-polymerase chain reaction with the universal primer set," Microbiol. Immunol. (1997) 41:209-213.	
	S28	MORICCA, et al., "Detection of Fusarium oxysporum f.sp. vasinfectum in cotton tissue by polymerase chain reaction," Plant Pathol. (1998) 47:486-494.	
	S29	MUDDIMAN, et al., "Characterization of PCR products from Bacilli using electrospray ionization FTICR mass spectrometry," Anal. Chem. (1996) 68:3705-3712.	
	S30	MUDDIMAN, et al., "Length and base composition of PCR-amplified nucleic acids using mass measurements from electrospray ionization mass spectrometry," Anal. Chem. (1997) 69:1543-1549.	
	S31	NAGPAL, et al., "Utility of 16S-23S rRNA spacer region methodology: how similar are interspace regions within a genome and between strains for closely related organisms?," J. Microbiol. Methods (1998) 33:211-219.	
	S32	NULL, et al., "Preparation of single-stranded PCR products for electrospray ionization mass spectrometry using the DNA repair enzyme lambda exonuclease," Analyst (2000) 125:619-626.	
	S33	NULL, et al., "Evaluation of sample preparation techniques for mass measurements of PCR products using ESI-FT-ICR mass spectrometry," Am Soc. Mass Spectrom. (2002) 13:338-344.	

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	S34	NULL and MUDDIMAN, "Determination of a correction to improve mass measurement accuracy of isotopically unresolved polymerase chain reaction amplicons by electrospray ionization Fourier transform ion cyclotron resonance mass spectrometry," <i>Rapid Comm. Mass Spectrom.</i> (2003) 17:1714-1722.	
	S35	NULL and MUDDIMAN, "Perspectives on the use of electrospray ionization Fourier transform ion cyclotron resonance mass spectrometry for short tandem repeat genotyping in the post genome era," <i>J. Mass Spectrom.</i> (2001) 36:589-606.	
	S36	NULL, et al., "Genotyping of simple and compound short tandem repeat loci using electrospray ionization Fourier transform ion cyclotron resonance mass spectrometry," <i>Anal. Chem.</i> (2001) 73:4514-4521.	
	S37	NULL, et al., "Implications of hydrophobicity and free energy of solvation for characterization of nucleic acids by electrospray ionization mass spectrometry," <i>Anal. Chem.</i> (2003) 75:1331-1339.	
	S38	PENG, et al., "Rapid detection of <i>Shigella</i> species in environmental sewage by an immunocapture PCR with universal primers," <i>App. Environ. Microbiol.</i> (2002) 68:2580-2583.	
	S39	POMERANTZ, et al., "Determination of oligonucleotide composition from mass spectrometrically measured molecular weight," <i>J. Am. Soc. Mass Spectrom.</i> (1993) 4:204-209.	
	S40	ROSS, et al., "Discrimination of single-nucleotide polymorphisms in human DNA using peptide nucleic acid probes detected by MALDI-TOF mass spectrometry," <i>Anal. Chem.</i> (1997) 69:4197-4202.	
	S41	SCARAMOZZINO, et al., "Comparison of Flavivirus universal primer pairs and development of a rapid, highly sensitive heminested reverse transcription-PCR assay for detection of flaviviruses targeted to a conserved region of the NS5 gene sequences," <i>J. Clin. Microbiol.</i> (2001) 39:1922-1927.	
	S42	SHAVER, et al., "Restriction fragment length polymorphism of rRNA operons for discrimination and intergenic spacer sequences for cataloging of <i>Bacillus subtilis</i> sub-groups," <i>J. Microbiol. Methods</i> (2002) 50:215-223.	
	S43	SRINIVASAN, et al., "Matrix-assisted laser desorption/ionization time-of-flight mass spectrometry as a rapid screening method to detect mutations causing Tay-Sachs disease," <i>Rapid Comm. Mass Spectrom.</i> (1997) 11:1144-1150.	
	S44	STEFFENS and ROY, "Sequence analysis of mitochondrial DNA hypervariable regions using infrared fluorescence detection," <i>Bio/Techniques</i> (1998) 24:1044-1048.	

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Application Number

10/326,642

Filing Date

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First Named Inventor

David J. Ecker

Group Art Unit

1637

Examiner Name

S. Chunduru

Attorney Docket Number

IBIS0001-106 (TIGR0005US)

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

[illegible]

Examiner Signature		Date Considered	
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Notice of References Cited

Application/Control No.

10/326,642

Applicant(s)/Patent Under
Reexamination
ECKER ET AL.

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Art Unit

1637

Page 1 of 1

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	F	US-			
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